Supreme Court, U.S.
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In the Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Federal Circuit is correct in holding that, because the *ultimate* issue of patent claim construction is one of law for the court under *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996), even the factual aspects of a district court's claim construction may be reviewed *de novo* on appeal.

2. Whether the Federal Circuit violated Fed. R. Civ. P. 52 and contravened precedents such as *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985), by rejecting admittedly plausible factual findings and credibility determinations supporting the district court's ultimate legal conclusion that the invention disclosed by petitioner's patent was not obvious.

3. Whether a patentee's strong showing of commercial success with a demonstrated nexus to an improvement invention covered by a patent can be disregarded as an indicator of the non-obviousness of the improvement because the patentee had exclusivity under earlier related patents.

RULE 14.1(b) AND 29.6 STATEMENT

Pursuant to Supreme Court Rule 14.1(b), petitioner Merck & Co., Inc. (Merck) states that all parties to the proceedings below appear in the caption of the case on the cover page. For clarity and to avoid any possible confusion, petitioner also notes that it is a completely separate legal entity from the unrelated German corporation that was the petitioner in this Court's recent decision in *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237 (June 13, 2005).

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent company and that there is no publicly held company that owns 10% or more of petitioner's corporate stock.

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OPINIONS BELOW

The majority and dissenting opinions of the court of appeals (App., *infra*, 1a-34a) are reported at 395 F.3d 1364. The opinion of the district court (App., *infra*, 43a-99a) is reported at 288 F. Supp. 2d 601. The order denying rehearing en banc and the dissenting opinion of three judges (App., *infra*, 35a-39a) are reported at 405 F.3d 1338.

JURISDICTION

The jurisdiction of the district court was invoked under 28 U.S.C. § 1338(a). The jurisdiction of the court of appeals was invoked under 28 U.S.C. § 1292(a)(1) and § 1295(a)(1). The court of appeals issued its judgment on January 28, 2005, and denied Merck's timely petition for rehearing on April 21, 2005. App., *infra*, 1a, 35a-39a. On June 23, 2005, Chief Justice Rehnquist extended the time within which to petition for a writ of certiorari to and including August 19, 2005. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION AND RULE INVOLVED

The statutory provision at issue is 35 U.S.C. § 103(a), entitled "Conditions for patentability; non-obvious subject matter," which provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rule at issue is Federal Rule of Civil Procedure 52(a), which provides:

> In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. * * *

STATEMENT

The FOSAMAX® medication developed by Merck was the first effective drug treatment for osteoporosis. Osteoporosis is a potentially debilitating disease afflicting millions, primarily post-menopausal women. It is caused by an imbalance in the body's natural process of destroying (or "resorbing") old bone and laying down new bone in its place. As people age, bone is resorbed faster than it is replaced. When the imbalance is too great, it can result in bones that are porous, brittle, and prone to fracture, leading to chronic pain, disability, and even death. Before the FDA approved Merck's daily FOSAMAX® products, post-menopausal women had only diet, exercise, and less satisfactory hormonal treatments to use against that serious disease.

This is the second patent infringement case related to FOSAMAX® between Merck and respondent Teva Pharmaceuticals USA, Inc. (Teva), a manufacturer of generic drugs.[1] The first case involved Merck's earlier '077 patent, which pioneered using the particular bisphosphonate in FOSAMAX®

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[1] Both cases were brought under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (also known as the "Hatch-Waxman Act").

(called "alendronate"), to treat osteoporosis, administered by "daily" dosing with 10-mg tablets (and then 5-mg tablets for prevention). See *Merck & Co., Inc.* v. *Teva Pharm. USA, Inc.*, 347 F.3d 1367 (Fed. Cir. 2003). In that case, the district court found infringement and upheld the validity and the patent term restoration of the '077 patent, and the Federal Circuit affirmed. *Id.* at 1369-74. Because Teva's challenge to Merck's '077 patent failed in the "daily" case, Teva is foreclosed from introducing generic alendronate tablets until after expiration of that patent and the related marketing exclusivity periods in February 2008. See 21 U.S.C. § 355(c)(2)(b).

The present patent infringement case involves Merck's '329 patent entitled "Method for Inhibiting Bone Resorption," in which the two claims at issue are directed to methods for treating or preventing osteoporosis through "once-weekly" administration of high alendronate doses. The parties have agreed that, when rewritten in independent form, the asserted claims read as follows (emphasis added):

> 23. A method for treating osteoporosis in a human comprising orally administering *about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis*, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.
>
> 37. A method for preventing osteoporosis in a human comprising orally administering *about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis*, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

The first question presented to this Court is squarely framed by the Federal Circuit's use of *de novo* review to disagree with the district court's construction of the highlighted phrases in claims 23 and 37 above.[2] The second and third questions chal-

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[2] As it did below, Merck refers to the "about 70 mg" and the "about 35 mg" phrases as shorthand for the entire disputed phrases, which appear in italics above.

lenge the Federal Circuit's increasing practice – in direct contradiction to this Court's cases – of reweighing a district court's detailed, plausible, and supported factual findings (in this case, as required by *Graham* v. *John Deere Co.*, 383 U.S. 1 (1966)), en route to reversing the district court's ultimate legal conclusion reached after a bench trial.

The FDA approved Merck's once-weekly FOSAMAX® dosing regimen in late 2000, and Merck began selling once-weekly tablets in November 2000. C.A. App. 718-19. Although Merck's 10- and 5-mg "daily" products were successful and enjoyed sales increases averaging more than $150 million each year before the once-weekly FOSAMAX® products were commercialized, the annual sales increases more than doubled after the improved once-weekly FOSAMAX® dosing regimen was introduced. C.A. App. 812-14, 817, 4007, 4006, 4340, 4344. That dramatic increase in physician and patient acceptance demonstrates that the invention created significant additional sales for the FOSAMAX® franchise.

A. State Of The Art in 1997: Widespread Belief That Alendronate Caused Dose-Related Side Effects

FDA approval for marketing FOSAMAX® as a high-dose, once-weekly tablet, as disclosed in the '329 patent, required Merck to undertake extensive clinical testing in support of a supplemental New Drug Application. 21 U.S.C. § 355(b); C.A. App. 527-28. The motivation for a weekly tablet was to avoid the inconvenient daily dosing regimen.[3] However, the '329 patent specification and the clinical studies it cited reflected the true state of the art at that time: strong apprehension over poten-

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[3] The dosing regimen for ingesting alendronate tablets required osteoporotic patients to take the tablets on an empty stomach with a full glass of water and to remain upright without eating for up to an hour after ingestion so as to avoid a broad spectrum of food substances that could destroy effectiveness and to avoid any prolonged contact of alendronate with the esophagus. C.A. App. 220-22, 600, 3786, 3832, 3951-52.

tial adverse side effects from oral administration of bisphosphonates at high doses.

After Merck's 10-mg daily FOSAMAX® tablets became publicly available, reports began surfacing of severe upper gastrointestinal injuries among osteoporotic patients. See, *e.g.*, C.A. App. 341-52, 3825-36. Ten articles detailing case reports of severe upper gastrointestinal injuries were published in peer-reviewed medical journals. C.A. App. 344-50, 354-56, 525-26, 3825-36, 3840-43, 3855-56, 3870-71. The report in the October 1996 *New England Journal of Medicine* was perhaps the most compelling for physicians. *Id.* at 348-51, 550-51, 3828-33, 4323. The lead author concluded that "alendronate can cause chemical esophagitis, including severe ulcerations in some patients." *Id.* at 3828-29, 3832, 348-52. In response, Merck notified the FDA and warned physicians of the potential for upper gastrointestinal injury from daily FOSAMAX® tablets, urging strict adherence to the dosing instructions. *Id.* at 615-16, 631-32, 664, 3782-84. Because such side effects were reported as dose-related, any suggestion to increase the dose would have directly contradicted accepted clinical experience. Among those who adopted and publicly advocated avoiding gastric injury by administering the bisphosphonates in smaller doses more often each day was Teva's bone and bisphosphonate expert in this case, Dr. Russell. C.A. App. 580.

The concern in the art about alendronate deterred any escalation to higher unit doses. C.A. App. 348-49. Merck itself submitted a report based on its clinical trials to the FDA explaining the clinical history that had led Merck initially to limit experimental doses for osteoporosis to 20 mg or less. C.A. App. 4060, 635-36, 639-40.

After the "side effect" incidents, Merck launched introspective studies to investigate the gastrointestinal side effects of alendronate and improve the treatment methods. Based on animal studies, Merck's inventors postulated that increasing dose size while decreasing frequency to weekly dosing might be as well or even better tolerated than the existing daily dosing regi-

men. The inventors first formulated this idea in May 1996. C.A. App. 610-611, 621. Because weekly dosing was one of many alternatives being advanced at Merck in 1996, the idea – which the Federal Circuit would later insist had been "obvious" – faced substantial skepticism within the company and was laid aside. *Id.* at 617-22. Only in mid-1997, after additional animal studies confirmed their thesis, did the inventors apply for a patent directed to administering sevenfold the daily dose on a weekly basis. *Id.* at 620-23, 713-14.

Until Merck's once-weekly studies, undertaken after the invention resulting in the '329 patent, no clinical investigator reported exposing osteoporotic women to unit doses over 20 mg of alendronate. Even statements by Teva before this lawsuit confirm the widespread perception and understanding of those skilled in the art about the potential for gastrointestinal injuries from high doses. C. A. App. 4414 (c.3, l.12-25, 34-43). The suggestion that a sevenfold dose would not increase gastrointestinal side effects seemed as surprising – at the time – as a suggestion that eating a whole pizza on Sunday night would cause no more heartburn than eating one slice of pizza a day.

The PTO issued Merck's '329 patent in 1999. Even though Teva could not enter the market until 2008, Teva recognized the superiority of Merck's "once-weekly" product, and filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to copy Merck's once-weekly 70-mg and 35-mg FOSAMAX® tablets before the expiration of the patent. In response, Merck filed this infringement suit under 35 U.S.C. § 271(e)(2).

B. The District Court Proceedings

Following a four-day bench trial, the district court ruled for Merck in an exhaustive opinion citing evidentiary support for the court's factual findings and making credibility determinations. App., *infra*, 43a-99a. Judge Farnan found that Merck provided an express definition in the specification of the disputed phrases in the claims (*id.* at 58a-62a) and rejected Teva's expert's contrary construction as unpersuasive (*id.* at 62a-64a). Teva sought to prove that a July 1996 article in a publication

called the *Lunar News* anticipated Merck's invention. Judge Farnan, however, rejected that contention as a matter of fact. *Id.* at 65a-73a. He also concluded that that *Lunar News* article and another similar article could not render the claims obvious. *Id.* at 73a-91a He further found that Merck's secondary considerations strongly weighed in favor of his ultimate legal conclusion that the invention was not obvious. *Id.* at 91a-94a..

1. The Claim Construction Issue

The district court held that the '329 patent expressly defines the "about 70 mg" and "about 35 mg" phrases by explaining that the terms account for the variability in active ingredient weight that would result from the use of alendronic acid derivatives. App., *infra*, 61a-62a. The specification says:

> Because of the mixed nomenclature currently in use by those of ordinary skill in the art, reference to specific weight * * * of a bisphosphonate compound in the present invention is on an acid active weight basis * * *. For example, *the phrase* "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis" *means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.*

C.A. App. 3594-95 (c10, l.65, to c.11, l.8) (emphasis added). The patent specification was exceptionally clear as to the meaning of the "about" phrase: any mention of a "specific weight" was to be standardized by reference to its acid form.

As defined by the specification, the "about 70 mg" and "about 35 mg" phrases adjust the weight of the active ingredient by taking into account variances in molecular weight for alendronic acid derivatives. As construed by the district court, the claim language requires that the amount of the alendronic acid derivative in the tablet be adjusted so that the tablet contains the same number of alendronate core molecules as 70 or 35 mg of alendronic acid. App., *infra*, 62a.

Attempting to parse the individual words from the defined phrase, Teva argued that "about" simply meant "approximately" – as if the patent had made no attempt to define the phrases that contain the word "about." The district court recognized that Teva's proposition that "about" means "approximately" was utterly implausible given that the patent's examples carefully denote the resulting quantity of alendronate derivative for its formulations to one-hundredth of a milligram. See App., *infra*, 62a-64a.[4]

The word "about" was placed within the quotation marks circumscribing the phrase being defined. See page 7, *supra*. The specification defines the phrase within the quotation marks as being calculated "based on 70 mg" and not "based on about 70 mg." Teva's construction required casting aside the patent's precise definition and moving the term "about" outside the quotation marks of the defined phrase or inserting the term "about" into the "based on 70 mg" definition.

Even Teva's expert, Dr. Russell, reluctantly but unambiguously accepted the '329 patent's explicit definition:

> Q. But they gave you that exact definition; correct?
>
> A. It's a curious use of the English language.
>
> Q. I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated in this?
>
> A. Possibly.

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[4] By accounting for the differences in the weights of alendronate derivatives, such usage is precise, not approximate. Examples 7 and 8 in the '329 patent provide for "about 35 mg of alendronate, on an alendronic acid active basis" and "about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis." C.A. App. 3599 (c19, l.13-15, 44-45). Those examples show that the adjusted weight for the alendronate derivative used is 45.68 mg and 91.35 mg respectively. *Id.* (c.19, l.20, 51).

Q. But that's what the definition says; right?

A. *That is the definition as it's described in the patent.*

C.A. App. 432-35 (emphasis added). Relying on both intrinsic and extrinsic evidence, the district court rejected Teva's construction based on the term "about." App., *infra*, 61a-64a.

2. Teva's Invalidity Defenses

Teva's invalidity defenses centered around two articles in the *Lunar News*. C.A. App. 3655-90. As the district court found, the *Lunar News* was not a scientific publication, but a quarterly newsletter of short, unattributed articles about multiple topics, published as a marketing tool by Lunar, a bone densitometer manufacturer. App., *infra*, 70a & n.1; C.A. App. 222-23, 321-22, 4957, 4959-60. Dr. Richard Mazess, Lunar's CEO, wrote most of the articles. C.A. App. 4954-56.

Dr. Mazess's one-page article entitled "Update: Bisphosphonate" in the July 1996 *Lunar News* observed that "[s]ome United States physicians are reluctant to treat because of: a) side effects; b) difficulty of dosing; and c) high costs ($700/year)." A3677. Near the end, without any supporting citation, that article suggests that "[e]ven alendronate potentially could be given in a 40 or 80 mg dose once/week to avoid dosing problems and reduce costs." *Id.*

The district court expressly found that "the prior art cited * * * demonstrates that the suggestion to give 40 or 80 mg of alendronate sodium to treat or prevent osteoporosis was not clinically useful or obvious in July 1997 because of the known dose-related gastrointestinal side effects." App., *infra*, 89a-90a. Moreover, even looking only at the two *Lunar News* articles,[5] the district court found that, "in light of the [clinical] case re-

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[5] Teva relied on a *Lunar News* article from April 1996, as well as the July 1986 article, in its obviousness defense. C.A. App. 3641. Suffering from even more defects than the July 1996 issue, the April 1996 *Lunar News* did not disclose any doses at all and failed to address the well-known expectation of gastrointestinal side effects with higher doses. *Id.*

ports, and the Chestnut study, in conjunction with observations written about alendronate by Dr. Fleis[c]h,[*] * * * the *Lunar News* references did not render the seven-fold daily dose of alendronate * * * obvious given the clearly documented and known dose related gastrointestinal side effects associated with high doses (over 20 mg) of oral alendronate." App., *infra*, 91a.

Those factual issues were disputed at trial, and were the subject of much evidence and expert testimony. The district court found that the evidence established that persons skilled in the art at the time of Merck's invention would have been skeptical of the *Lunar News* suggestion to try 40- and 80-mg doses in light of the dose-related gastrointestinal problems. App., *infra*, 90a. The support for that finding came from the trial evidence from the acknowledged experts in the art, including Drs. Papapoulos, Chestnut, Fleisch, and Fennerty, and even Teva's Dr. Russell. The district court expressly noted that Dr. Fennerty was "very credible" when explaining why any physician would have been "extraordinarily concerned" to suggest a 40- or 80-mg dose for osteoporotic patients. *Id.*

In contrast, the district court recognized that Dr. Mazess, the author of the *Lunar News* articles, "[did] not possess an MD, has no formal training in pharmacology, and obtained his bachelors degree and Ph.D in anthropology." App., *infra*, 70a n.1. Given that Judge Farnan also found for purposes of the *Graham* factors that a person of ordinary skill in the art was "an individual who would have an M.D. and/or Ph.D. and was working in the field of and doing research on osteoporosis" (App., *infra*, 84a), Dr. Mazess's expertise fell short of the osteoporosis treatment experts that were the source of the other evidence at trial. To rule in Merck's favor, the district court did not have to go so far as to deem Dr. Mazess not an expert at all; rather, it sufficed to find Dr. Mazess *less credible* than other experts – just what finders of fact do in all types of complex cases.

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[*] As the district court recognized, Dr. Fleisch is known as the "father of bisphosphonates" due to his extensive work and authorship of the leading treatise in the field. App., *infra*, 85a.

Finally, the district court found that "the significant secondary considerations offered by Merck undermine any claim of obviousness." App., *infra*, 94a. The court found Merck's expert testimony "persuasive" in explaining the increased sales after the launch of the once-weekly FOSAMAX® product, without any corresponding increase in expenditures, and noted a sharp increase in physician adoption of FOSAMAX® after introduction of the weekly regimen. App., *infra*, 91a-92a. In contrast, the district court found Teva's expert to be "unpersuasive." App., *infra*, 93a.

C. Proceedings In The Federal Circuit

In a 2-1 decision, the Federal Circuit reversed the district court's judgment, disagreeing with its claim construction and holding the asserted claims invalid for obviousness as a matter of law. See App., *infra*, 2a.

1. The Reversal On Claim Construction

In reversing the district court's claim construction, the court first redefined the parties' dispute as being over the meaning of the word "about" rather than the entirety of the phrases in the claims where that term appears. Declaring the definition of those phrases in the specification "ambiguous," the Federal Circuit believed itself free to give "about" its ordinary meaning of "approximately" because the specification had not redefined that term. App., *infra*, 2a, 10a & n.7, 15a.

But the meaning of the term "about" was never in issue at the trial and was never litigated. The entirety of the phrase was the issue. To sidestep Merck's irrefutable position about what the words of the patent specification actually say, the majority simply declared that the drafters made a mistake: "While Merck's grammatical savvy is noted, we believe that the omission of a second 'about' is likely an inadvertent error rather than the product of meticulous claim drafting." App., *infra*, 13a n.8. Not even Teva had asserted such an inadvertent drafting error, and there was *no* evidence to suggest one.

2. The Reversal Of The Nonobviousness Holding, Including The Nullification Of Merck's Demonstrated Commercial Success Evidence

Separately, the Federal Circuit held that Merck's two claims were invalid as a matter of law in light of the two *Lunar News* articles by reaching its own conclusion of obviousness, and then globally reweighing the evidence, making new findings on appeal, and – with unusual candor – universally rejecting contrary findings as "clearly erroneous." See, *e.g.*, App., *infra*, 22a (emphasis added) ("*to the extent* that the district court interpreted the scope of the prior art *otherwise*, that was clear error"). That inverted approach to reviewing the district court's strict and careful adherence to this Court's *Graham* factors accorded no deference to the district court's detailed findings on several pivotal and clearly disputed factual issues.

In addition, the Federal Circuit took a surprising approach to the law of secondary considerations – law emanating from *this* Court's *Graham* v. *John Deere* decision and numerous even earlier decisions of this Court. The court declared that Merck's dramatic "commercial success" evidence had "no force" on the ground that Merck's prior existing patent had "legally barred" anyone else from pursuing or testing any improvements to Merck's prior "daily" invention. App., *infra*, 23a-24a. Under that approach, an existing patent owner could ever prove commercial success of an improvement patent, in the pharmaceutical field or any other field.

3. The Dissenting Opinions

a. Judge Rader's Dissent

Judge Rader dissented from the panel decision, asserting that "[t]his case shows the consequences of paying only lip service to the often-cited, but rarely-followed lexicographer rule and the basic jurisprudential principle of according trial courts proper deference." App., *infra*, 26a. He observed that the Federal Circuit's claim construction rules are used as either "a subtle way for judges to impose their own semantic subjectivity

on claim terms" or "a way for judges to import limitations not included in the claims." *Id.*

Judge Rader explained why the word "about" was inseparable from the entire phrase defined in the specification, and pointed out that the specification set off the entire phrase in quotation marks, including the term "about," and expressly stated what that phrase "means" for purposes of the patent. App., *infra*, 28a-29a. Judge Rader understood that the specification explained why the phrase was being defined – "[b]ecause of the mixed nomenclature currently in use by those o[f] ordinary skill in the art" – and revealed the scientific reason for including "about" in its definition – "[a] salt or a mixture may require a different weight to achieve the same number of bisphosphonate molecules present in 70 mg of alendronate." *Id.* at 29a-30a.

Judge Rader concluded by decrying his own court's inability or refusal to give deference to the efforts and conclusions of district courts in matters of claim construction. "This was the classic 'close case,' so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with [Merck] and two federal judges agreed with [Teva]." App., *infra*, 32a. Despite the district court's "superior tools and time" to evaluate the record, the witnesses, and the evidence, he noted that the Federal Circuit often "becomes enamored with its own analysis of a very close issue and reverses the district court." *Id.* As he put it, the court has a double-edged "'truth in advertising' problem" when it comes to giving deference to district courts. *Id.* at 33a-34a.

b. The Dissent Of Three Additional Judges

Judge Lourie, joined by Chief Judge Michel and Judge Newman, dissented from the denial of rehearing en banc. App., *infra*, 38a-39a. In their view, the panel majority erroneously concluded that commercial success is not probative because "others were legally barred" from commercially testing certain ideas and because the majority erred in linking commercial success to the failure of others. App., *infra*, 38a.

Judge Lourie explained that "[c]ommercial success is a question of fact, and, once it is established, as found here by the trial court, the only other question is whether the success is attributable to the claimed invention ('nexus')." App., *infra*, 38a. In the view of those dissenting judges, "[t]he panel's rule is especially unsound in the context of an improvement patent, as here, because it holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention." *Id.* at 38a-39a. "[T]he full court should have reheard the appeal to eliminate the confusion in the law that the panel opinion creates." *Id.* at 39a.

REASONS FOR GRANTING THE PETITION

When Congress created the United States Court of Appeals for the Federal Circuit in 1982, it centralized the *appellate* function in patent cases. The *trial* function remains with district courts around the country, following normal trial procedures. Nothing gives the Federal Circuit more reason than any other appellate court to substitute its judgment on *factual* issues for that of a district court that has held a trial. Yet the Federal Circuit is doing just that – by allocating to itself the power of *de novo* review, by giving lip service to the "clearly erroneous" rule but then transparently failing to apply it, and most recently by robbing of all substance an important criterion established by this Court for determining obviousness.

All of this has provoked howls of outrage from some of the Federal Circuit's own judges. See App., *infra*, 26a (Rader), 38a-39a (Lourie); *Phillips* v. *AWH Corp.*, 376 F.3d 1382, 1384 (Fed. Cir. 2004) (Mayer, C.J., dissenting from en banc order) ("Until the court is willing to reconsider its holdings * * * that claim construction is a pure question of law subject to *de novo* review in this court, any attempt to refine the process is futile. * * * [S]huffling our current precedent merely continues a charade * * *."); *Phillips* v. *AWH Corp.*, No. 03-1269, 2005 WL 1620331, at *22-*26 (Fed. Cir. July 12, 2005) (en banc) (Mayer, J., dissenting). There is a war on within the Federal Circuit, and only this Court can stop the fighting and bring the Federal

Circuit's approach to factual issues in line with the approach of other appellate courts.

The open disagreement among judges of the Federal Circuit suggests that now is a particularly appropriate occasion for this Court to oversee how that court is handling its exclusive appellate docket. In 1986 this Court felt constrained to remind the Federal Circuit of the proper role of appellate courts in reviewing findings of fact. *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. 809, 811 (1986). The Federal Circuit has not been alone in needing such supervision from this Court for failing to defer on factual issues.[7] Moreover, this is a case in which the standard of review mattered – the district court's exhaustive opinion, heavily dependent on factual findings including credibility determinations after a trial, could not have been reversed on either claim construction or obviousness by a court truly engaged in deferential review of the facts. And one of the most important patents in the pharmaceutical field has been invalidated because the Federal Circuit overstepped its bounds.

Furthermore, this case usefully complements *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996). In that case this Court almost a decade ago held that patent claim construction is an issue exclusively for "the court" but said nothing to indicate whether "the court's" findings following a trial should be reviewed deferentially – as factual findings underlying an issue reserved for judicial determination usually are. See, *e.g.*, *Ornelas* v. *United States*, 517 U.S. 690, 699 (1996); *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 402 (1990); *Pierce* v.

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[7] See, *e.g.*, *Amadeo* v. *Zant*, 486 U.S. 214, 223 (1988); *Icicle Seafoods, Inc.* v. *Worthington*, 475 U.S. 709 (1986); *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985); *Inwood Labs., Inc.* v. *Ives Labs., Inc.*, 456 U.S. 844 (1982); see also *Ornelas* v. *United States*, 517 U.S. 690, 699 (1996) (after holding that the standard of appellate review of ultimate determinations of probable cause or reasonable suspicion is *de novo*, "hasten[ing] to point out that a reviewing court should take care • • • to review [underlying] findings of historical fact only for clear error"). See generally 1 CHILDRESS & DAVIS, FEDERAL STANDARDS OF REVIEW § 2.08 (3d ed. 1999).

Underwood, 487 U.S. 552, 560 (1988); *Miller* v. *Fenton*, 474 U.S. 104, 114-115 (1985).

The court compounded its lack of deference by announcing an erroneous, new, and far-reaching principle of law that the commercial success criterion announced in this Court's cases can be disregarded whenever a patentee obtains an improvement patent. On all three questions presented, the Federal Circuit has decided important issues contrary to this Court's precedents, and this case presents an excellent vehicle for addressing Federal Circuit practices that have become problematic as the court regularly reverses district courts' proper, fact-dependent holdings on both claim construction and obviousness.

I. This Court Should Review The Federal Circuit's Strident But Erroneous View That There Is No Evidentiary Factfinding In Patent Claim Construction

The Federal Circuit's *de novo* standard of review as applied indiscriminately to facts underlying claim construction has afforded that court the extraordinary license to reverse district court findings that could not have been reversed under any other standard. The *de novo* standard, adopted by the Federal Circuit in two en banc decisions and recently reaffirmed en banc, is ripe for this Court's review. The standard is plainly wrong, and this case presents an excellent vehicle for reviewing it.

A decade ago, the Federal Circuit held in *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 897 (Fed. Cir. 1995) (*Markman I*), aff'd in part, 517 U.S. 370 (1996) (*Markman II*), that "the interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court." 52 F.3d at 970. The en banc also declared that there were no findings of fact to be made by a court (*id.* at 981 (emphasis added)):

> Through this process of construing claims by, among other things, using certain extrinsic evidence that the court finds helpful and rejecting other evidence as unhelpful, and resolving disputes en route to pronouncing the meaning of

> claim language as a matter of law based on the patent documents themselves, *the court is not crediting certain evidence over other evidence or making factual evidentiary findings.* * * * The district court's claim construction, enlightened by such extrinsic evidence as may be helpful, is still based upon the patent and prosecution history. *It is therefore still construction, and is a matter of law subject to de novo review.*

In *Markman II*, this Court held that "the construction of a patent * * * is exclusively within the province of the court," 517 U.S. at 372, but did not call the question one of law or address the standard of appellate review. Instead, this Court focused on allocating claim construction as between court or jury, and concluded that "judges, not juries, are the better suited to find the acquired meaning of patent terms." *Id.* at 388. The Court unmistakably focused, however, on the claim construction task as performed by *trial* judges (*id.* at 389-90 (emphasis added)):

> [I]n these cases a jury's capabilities * * * are much less significant than a trained ability to ***evaluate the testimony*** in relation to the overall structure of the patent. The decisionmaker vested with the task of construing the patent is in the better position to ascertain whether an expert's proposed definition fully comports with the specification and claims and so will preserve the patent's internal coherence. We accordingly think there is sufficient reason to treat construction of terms of art like *many other responsibilities that we cede to a judge in the normal* ***course of trial, notwithstanding its evidentiary underpinnings***.

Nonetheless, again sitting en banc in *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998), the Federal Circuit announced that under *Markman II* it was permitted to "review claim construction *de novo* on appeal including any allegedly fact-based questions."

The Federal Circuit insists that claim construction is a question of law for the court, and that it follows that the appellate court is entitled to give all aspects of claim construction *de novo*

review without deference to factual findings. Those concepts are not the same, however, and not all questions reserved for the court are reviewed *de novo*. Indeed, there is no reason why claim construction should be different in this regard from patent validity, as to which this Court has emphasized that "the ultimate question * * * is one of law," but pointed out in the same sentence that a subsidiary question "lends itself to several basic *factual* inquiries." *Graham*, 383 U.S. at 17 (emphasis added). Just as *Graham* acknowledged factual inquiries underlying obviousness, *Markman II* acknowledged "evidentiary underpinnings" of claim construction, 517 U.S. at 390. The two issues should receive parallel treatment.

Last month, the Federal Circuit issued its eagerly awaited en banc decision in *Phillips* v. *AWH Corp.*, No. 03-1269, 2005 WL 1620331 (Fed. Cir. July 12, 2005). Despite numerous amicus briefs urging it to abandon the holdings of *Markman I* and *Cybor*, the court without substantive comment, and over vehement dissent, "decided not to address that issue at this time * * * [and] therefore le[ft] undisturbed [its] prior en banc decision in *Cybor*." 2005 WL 1620331, at *20. The three en banc holdings that there is no deference-worthy factual component to claim construction are the source of the Federal Circuit's current and internally recognized quagmire.

The fiction that district courts never weigh evidence or find facts when deciding the meaning of patent claims has – in little more than a decade – proved itself to be unworkable and increasingly arbitrary.[8] The most recent and comprehensive study

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[8] See *Phillips* v. *AWH Corp.*, 376 F.3d at 1384 (Mayer, C.J., dissenting from en banc order) ("Nearly a decade of confusion has resulted from the fiction that claim construction is a matter of law, when it is obvious that it depends on underlying factual determinations which, * * * if disputed, are * * * reviewable on appeal for clear error."); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("Now more than ever I am convinced of the futility, indeed the absurdity, of this court's persistence in adhering to the falsehood that claim construction is a matter of law devoid of any factual component. * * * [A]ny attempt to fashion a coherent

of all Federal Circuit decisions since *Markman II* through 2003 calculated that the reversal rate for appealed claim terms is 34.5%. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 233 (2005) (citing other empirical studies). That extremely high reversal rate is well over three times the average for all circuits combined, which has been below 10% each year between 2001 and 2004.[9] Professor Moore concluded that "[t]he problem is getting worse, not better," noting that, since *Markman II*, there should be more predictability in claim construction, not less, and the reversal rate should be going down, not up, but the opposite is true in both respects. *Id.* at 245-47.

Not only has the Federal Circuit's flawed premise that there is no fact finding in claim construction directly caused increased unpredictability, uncertainty, litigation costs, and reversal rates, but also it has damaged the court's credibility and legitimacy in the eyes of both litigants and district courts. *Phillips*, 2005 WL 1620331, at *24 (Mayer, J., dissenting) ("that claim construction is dependent on underlying factual determinations has been verified by our experience, which shows that reviewing these questions de novo has not clarified the law, but has instead distort[ed] the appellate process, causing confusion among the district courts and bar") (internal quotation marks omitted). Any hope that the Federal Circuit's *en banc* decision in *Phillips* might confront the real problem ended when the court declined to disturb its prior decision in *Cybor*. See 2005 WL 1620331, at *20. Hence, the Federal Circuit's unjustifiable fiction authorizing its form of "*de novo* review" should not escape this Court's oversight any longer.

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standard under this regime is pointless, as illustrated by our many failed attempts to do so * * *.").

[9] See http://www.uscourts.gov/caseload2004/tables/B05Mar04.pdf; http://www.uscourts.gov/caseload2003/tables/B05Mar03.pdf; http://www.uscourts.gov/caseload2002/tables/B05Mar02.pdf; http://www.uscourts.gov/caseload2001/tables/B05Mar01.pdf.

To be sure, construing patent claims involves construing a written instrument, a task better allocated to judges than to juries. But that does not mean claim construction has no factual component. As a matter of substantive patent law, the issue is not what the claims *mean to judges*, but what they mean to "those skilled in the art to which the invention pertains or with which it is most nearly connected." *Phillips*, 2005 WL 1620331, at *5 (opinion of the court) (quoting *In re Nelson*, 280 F.2d 172, 181 (CCPA 1960)). That is a matter most frequently resolved by weighing evidence, not by parsing legal principles. Factual, not legal, inquiry is necessary to educate a court about the views of those skilled in the art, especially because "patentees frequently use terms idiosyncratically" (*Phillips*, 2005 WL 1620331, at *6), as was done in this case. It follows that the standard of appellate review is that usually applied to factual findings underlying a question for the court. See note 7, *supra*; pages 15-16, *supra*; *Phillips*, 2005 WL 1620331, at *23 (Mayer, J., dissenting). For the Federal Circuit to hold otherwise, simply because it believes the *ultimate* issue is one of law, is nothing but a power grab away from district judges.[10]

Even with proper deference accorded to district courts under Rule 52(a), some claim construction issues may be decided as a matter of law, when, for example, the patent itself and other evidence show that there is only one *reasonable* way to construe the affected term.[11] In other instances, however, a pat-

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[10] See App., *infra*, 32a-34a (Rader, J.., dissenting); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("This court was created for the purpose of bringing consistency to the patent field. * * * Instead, we have taken this noble mandate, to reinvigorate the patent and introduce predictability to the field, and focused inappropriate power in this court. * * * [T]he resulting mayhem has seriously undermined the legitimacy of the process, if not the integrity of the institution.").

[11] Ironically, this was such a case. Yet the majority dismissed the only reasonable reading of the patent's explicit definition as mere "grammatical savvy," and insisted on substituting its judgment that there was an "inadvertent error" for the judgment of the district court, the words of the patent, and the expert testimony. App., *infra*, 13a n.8. By disregard-

ent's intrinsic evidence will be obscure or inconclusive. Shortly after *Markman I*, the Federal Circuit in *Hoechst Celanese Corp.* v. *BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996), reviewed the intrinsic evidence, experimental data, expert testimony, and dictionaries to determine the meaning of the disputed term in the specification's definition, while being careful to say that it did not accord any deference to the district court's findings or credibility determinations. Nevertheless, the Federal Circuit conceded it was "necessary to rely on the evidence presented at the trial and credit certain evidence over other evidence" when construing claims. *Id.* at 1579. That is what all courts do in such situations, even if the Federal Circuit's en banc decisions in *Cybor* and *Markman I* insisted they do not.[12]

A court's determination of the meaning of a disputed claim phrase, in an environment that requires consideration of what the claim terms meant to a person of skill in the art at the time, inevitably involves weighing conflicting evidence. Here, for example, Judge Farnan explicitly found Teva's expert "unpersuasive." App., *infra*, 64a. Resolving such conflicts requires factfinding, the prototypical task for which district courts are best suited and entitled to deference. See *Zenith Radio Corp.* v.

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ing the patent's definition in its entirety, the Federal Circuit gutted a patentee's ability to act as its own lexicographer to avoid the uncertainties of a future contested claim construction. See App., *infra*, 26a-32a (Rader, J., dissenting).

[12] See App., *infra*, 32a (Rader, J., dissenting) ("Despite the district court's superior tools and time to evaluate the complete record, to hear and inquire from expert and fact witnesses, to delve into countless related details, to probe the scientific and semantic context, and to entertain argument as long as necessary for clarity, this court with its reading three briefs before its half-hour hearing becomes enamored with its own analysis of a very close issue and reverses the district court."); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("[A]fter * * * whipping the bar into a frenzy of expectation, we say nothing new, but merely restate * * * that we will decide cases according to whatever mode or method results in the outcome we desire * * *. [T]here can be no workable standards by which this court will interpret claims so long as we are blind to the factual component of the task.").

Hazeltine Research, Inc., 395 U.S. 100, 123 (1969). What this Court said last Term about tax cases is no less true of patent cases: "The officer who hears witnesses and sifts through evidence in the first instance will have a comprehensive view of the case that cannot be conveyed full strength by a paper record." *Ballard* v. *Comm'r*, 125 S. Ct. 1270, 1283 (2005). "It is, of course, true that credibility judgments have to be made about the experts who testify in patent cases" (*Markman II*, 517 U.S. at 389), and that fact – although no reason to assign factfinding to juries – is very much a reason to review deferentially on appeal the factual component of claim construction. One month after *Markman II*, this Court announced a *de novo* standard of review for probable-cause determinations in search-and-seizure cases but insisted on "clear error" review for "findings of historical fact." *Ornelas*, 517 U.S. at 699. This Court's opinions thus disprove the Federal Circuit's inference that, because claim construction is for the court, *de novo* review applies to all aspects of the issue.

This "standard of review" controversy generated by the Federal Circuit's en banc precedent extends well beyond the enormous dollars at issue in this case. This case provides an excellent vehicle to resolve the dispute within the Federal Circuit and rampant within the affected legal community over whether district courts engage in factfinding subject to Rule 52(a) when construing the meaning of patent claims.[13] When the judicial

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[13] In addition to the strong disagreement within the Federal Circuit reflected by the dissenting opinions in the en banc cases, see, *e.g.*, *Lucas Aerospace, Ltd.* v. *Unison Indus., L.P.*, 890 F. Supp. 329, 333-34 (D. Del. 1995) ("when the Federal Circuit Court of Appeals states that the trial court does not do something that the trial court does and must do to perform the judicial function, that court knowingly enters a land of sophistry and fiction"); Burgess, Comment, *Simplicity At The Cost Of Clarity: Appellate Review Of Claim Construction And The Failed Promise of Cybor*, 153 U. PA. L. REV. 763 (2004); Zura, *Looking For Fire Amidst The Smoke – Is The Federal Circuit Really Exceeding Its Appellate Authority In Patent Infringement Cases?*, 12 U. BALT. INTELL. PROP. L.J. 1 (2003); Staheli, Comment, *Deserved Deference: Reconsidering*

process for claim construction allows the Federal Circuit to invent a factual premise advanced by no party and supported by no evidence – that an inadvertent drafting error took place (App., *infra*, 13a n.8) – it becomes clear that factfinding is occurring in the wrong court. And when the Federal Circuit supplants the trial court's plausible choice between two reasonable interpretations of Merck's "ambiguous" definition for the disputed phrase in claims 23 and 37 (App., *infra*, 13a), it is apparent that the deferential review provisions of Rule 52(a) are being ignored.[14] As Judge Rader noted, "In this case, this court eschews all deference, a particularly striking choice in the face of a very close case and a district court whose diligent and intelligent process and resolution earned more respect than it received." App., *infra*, 33a (dissenting opinion).

The Federal Circuit will never voluntarily relinquish its self-granted power of unrestricted review. See App., *infra*, 10a n.7; *Phillips*, 2005 WL 1620331, at *20. The Federal Circuit has begun expanding its flawed "*de novo*" rationale into other areas of patent law "related to" claim construction. See, *e.g.*, *Exxon Research & Eng'g Co.* v. *United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001) (holding the invalidity defense of indefiniteness was sufficiently tied to claim construction that it did

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The De Novo Standard Of Review For Claim Construction, 3 MARQ. INTELL. PROP. L. REV. 181 (1999).

[14] In a footnote, the majority defensively asserted that "[i]t makes no difference to this conclusion [of invalidity] whether the court begins with the claim construction set forth by the panel or the dissent." App., *infra*, 16a n.10. Clearly, however, the parties' claim constructions were different, both could not have been right, and there is no question that obviousness can be properly determined only in view of the correct claim construction. The Federal Circuit, indeed, contradicted its own footnote by beginning its obviousness discussion by saying, "*In light of* the corrected claim construction we find reversible error in the district court's obviousness analysis." App., *infra*, 15a (emphasis added). If claim construction truly did not matter, the issue would not have been hotly litigated throughout this case and the Federal Circuit would not have addressed that issue at length on appeal.

not involve underlying issues of fact) (citing *Cybor*). Thus, as further evidenced by its obviousness ruling in this case, the Federal Circuit's basic misunderstanding of "*de novo* review" is not confined to claim construction issues, but infects that court's approach to anything that it perceives as a "legal issue." This Court should not wait to correct that entrenched and erroneous practice.

II. The Court Should Review The Federal Circuit's Practice Of Using Its *De Novo* Review Of Legal Issues To Reweigh Evidence And Substitute Its Views For A District Court's Factual Findings

In *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. at 811, this Court summarily vacated a Federal Circuit decision that had reversed a district court's holding of obviousness, noting that the determinations on the *Graham* factors and secondary considerations (including commercial success), "at the least, ought to be subject to [Rule 52(a)]." Now, almost 20 years later, the Federal Circuit needs a refresher course.

Of course, since 1986, the Federal Circuit's decisions on obviousness have routinely cited Rule 52(a) and the *Graham* factors. See App., *infra*, 8a, 16a. Just as routinely, however, the Federal Circuit pays lip service to Rule 52(a) but then reweighs the conflicting evidence to conform to its own conclusion on the ultimate legal issue. See App., *infra*, 26a (Rader, J., dissenting).

This case is the latest and most striking example of a bench trial nullified by the Federal Circuit's self-granted license to review findings of fact without any real deference.[15] As its own opinion in this case illustrates, the Federal Circuit arrives at its outcome, and then globally mows down any contrary finding with a declaration of clear error. That result-oriented approach

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[15] See Rooklidge & Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort With Its Appellate Role*, 15 BERKELEY TECH. L.J. 725 (2000) (explaining the Federal Circuit's increasing tendencies toward appellate factfinding, creating new records on appeal, and raising new arguments on its own, citing illustrative cases).

of first deciding the legal issue *de novo* and then going back to review the underlying factual determinations cannot possibly accord the proper Rule 52(a) deference to a district court's findings on disputed factual issues. See App., *infra*, 32a-34a (Rader, J., dissenting).

"If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently." *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 573-74 (1985). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Id.* at 574. Here, the district court's exhaustive findings on disputed factual issues reached after a fully litigated bench trial could not have been legitimately cast aside.

For present purposes, this Court need only recognize that the district court's factual findings are both plausible and fully supported by the cited evidence and expert testimony. See App., *infra*, 90a (finding Merck's expert "very credible"); *id.* at 93a (finding Teva's expert "unpersuasive"). "When findings are based on determinations regarding the credibility of witnesses, Rule 52(a) demands even greater deference to the trial court's findings." *Bessemer City*, 470 U.S. at 565.

But the Federal Circuit did more than substitute one plausible set of findings for the district court's different findings. The district court found that persons skilled in the art at the time of Merck's invention would have been skeptical of the *Lunar News* suggestion to try 40- and 80-mg doses in light of the dose-related health problems. App., *infra*, 90a. The Federal Circuit accepted that finding (App., *infra*, 19a), but then proceeded to elevate Dr. Mazess's alleged expertise over all others, holding that "the district court failed to give proper credit to the fact that Dr. Mazess was an expert in osteoporosis." App., *infra*, 22a. Any such issue of "proper credit" is a disagreement on weight, which should not have been revisited on appeal or circumvented simply by declaring Mazess an "expert."

The Federal Circuit's post-trial revision of Dr. Mazess's skill level is disingenuous. Even if Dr. Mazess qualified as an expert, the trier of fact was entitled to find him *less credible* than other experts, and did so. App., *infra*, 90a-91a. The testimony the district court accepted was that the *Lunar News* suggestion would have been incredible to anyone skilled in the relevant art. Hence, only someone unskilled in the relevant art would even have suggested investigating 80-mg doses when everyone with actual skill in the art was unwilling to give osteoporosis patients more than 20 mg.

In making its *Graham* findings on the scope and content of the prior art and the differences between that art and the claimed inventions, the district court properly looked at what a number of individuals skilled in the art knew and examined all of the art before finding that the serious side effect concerns would have rendered the naked suggestion in the *Lunar News* articles to try higher doses "not clinically useful." App., *infra*, 90a. That treatment of those two articles was entirely proper. Even if they had been "published in peer-reviewed journals or authored by one skilled in the art," there could be no clear error in finding that they would not have overcome what one skilled in the art would have understood from the body of prior art as a whole.

Confining its analysis to the two *Lunar News* articles, the Federal Circuit improperly circumscribed the prior art and disregarded everything that taught away from the article's invitation to try. See *United States* v. *Adams*, 383 U.S. 39, 51-52 (1966) (known disadvantages in the prior art which would naturally discourage the search for new inventions may be considered in determining obviousness). Here, because those skilled in the art in 1997 would not have followed the unsupported July 1996 *Lunar News* suggestion, the finding that the *Lunar News* articles could not have overcome the teachings of the prior art as a whole again could not have been clearly erroneous.[16]

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[16] The prior art and the acknowledged skepticism in the art instead created a clear expectation that the *Lunar News* suggestion would fail. Such a demonstrated expectation of failure is the antithesis of a reason-

On appeal the Federal Circuit found that a motivation would have existed to reduce the 80/40-mg dose suggestions in *Lunar News* to the claimed 70/35-mg doses. App., *infra*, 16a-17a. As the district court realized, however, that was not even the correct inquiry. Instead, the relevant analysis was whether there would have been any motivation in the art to increase the dosage beyond the 20-mg level believed to cause unacceptable side effects. App., *infra*, 91a. Not even the Federal Circuit could find that anyone in 1997 would have been motivated to do that, which reveals that any necessary teaching or motivation could have been found only in hindsight.

If there was ever a case in which Rule 52(a) should have compelled accepting a district court's findings, it is this one. This case is therefore an excellent vehicle by which to correct the Federal Circuit's clear misapprehension of the concept and scope of its appellate "*de novo*" review while sparing this Court from becoming bogged down in the underlying factual disputes already plausibly resolved by the district court.

III. This Court Should Review The Federal Circuit's Ruling Nullifying The Probative Value Of A Patentee's "Commercial Success" Evidence Related To Its Improvement Patent

The Federal Circuit also held that the district court "erred in its weighing of secondary considerations of non-obviousness." App., *infra*, 22a. That, too, was not the Federal Circuit's prerogative to reassess. See *Inwood Labs., Inc.* v. *Ives Labs., Inc.*, 456 U.S. 844, 856 (1982) ("Determining the weight and credibility of the evidence is the special province of the trier of fact."). This issue shares with the first two issues the characteristic that the Federal Circuit has unjustifiably substituted its judgment for that of the trier of fact, but it also involves separate *legal* considerations as to which the Federal Circuit departed from this Court's cases.

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able expectation of success. See, *e.g.*, *Boehringer Ingelheim Vetmedica, Inc.* v. *Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003).

The commercial success criterion strongly supported the non-obviousness of Merck's "once-weekly" patent. As noted above, sales of FOSAMAX® skyrocketed following the insight that once-weekly doses could be effective without increased potential for gastrointestinal distress. Judge Farnan appropriately placed "importance" on this factor. App., *infra*, 93a.

In so doing, he followed this Court's cases faithfully. In *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876), the Court recognized commercial success as something that could "justify the inference" that an innovation "was, in truth, invention." The Court phrased it more strongly in *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916): commercial success, "of itself, is persuasive evidence of * * * invention." In *Graham* v. *John Deere Co.*, 383 U.S. at 17-18, the Court reiterated (following a change in statutory law) that "[s]uch secondary considerations as commercial success" are important, and noted that "failure of others" is a *separate* "secondary consideration[]." See also *Goodyear Tire & Rubber Co.* v. *Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944); *Krementz* v. *The S. Cottle Co.*, 148 U.S. 556, 560 (1893).

This Court, not the Federal Circuit, originated the commercial success criterion, and the Federal Circuit was not at liberty to reduce it essentially to a nullity whenever a patentee obtains an improvement patent. Yet the Federal Circuit declared that Merck's "commercial success" evidence "has *no force* in this case" because "others were legally barred from commercially testing the Lunar News ideas" due to Merck's other patent rights. App., *infra*, 23a (emphasis added). That ignores not only the decisions of this Court's cited above, but also the Constitution. See U.S. CONST. Art. I, § 8, cl. 8. Given that Congress is to "secure[e] for limited times to * * * Inventors the exclusive right to their * * * Discoveries" in exchange for full disclosure so that the public may benefit from and build on the patent's teachings, the Federal Circuit's misplaced reliance on others' having no incentive to improve patented inventions before patent expiration directly undermines

the fundamental purposes of the patent system. See 35 U.S.C. § 101 (patentable inventions include "any new and useful improvement"); *Gen. Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938) ("most inventions represent improvements on some existing article, process or machine"); see also *Graham*, 383 U.S. at 7 (Thomas Jefferson's "improvements on plows, to mention but one line of his inventions, won acclaim and recognition on both sides of the Atlantic").

The Federal Circuit's rule nullifying a prior patentee's commercial success evidence will also unjustly discriminate against patentees who continue to enrich the public by improving their inventions. If the rule is allowed to stand, a third party that develops and patents an improvement to an earlier patented invention can support its non-obviousness case by proving commercial success and nexus but the earlier patentee would be foreclosed from doing so. That distinction makes no sense, and threatens to undermine the patent system's basic goals of encouraging innovation and full disclosure to the public.

On that basis alone, the Federal Circuit's far-reaching new rule should be reviewed and reversed. See App., *infra*, 38a-39a (Lourie, J., dissenting). But the Federal Circuit's other justifications for nullifying Merck's strong commercial success evidence for its improved dosing regimen in the '329 patent are equally meritless. For example, the Federal Circuit ignored 35 U.S.C. § 271(e)(1), which provides certain "safe harbors" from infringement for testing of a new drug product. See *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2381 (2005); *Eli Lilly & Co.* v. *Medtronic Inc.*, 496 U.S. 661 (1990). Indeed, Teva was in fact doing research and seeking patents on other alendronate inventions, and had a strong incentive to develop Merck's present invention, both for purposes of licensing Merck and for obtaining its own exclusivities extending beyond the expiration of Merck's '077 patent. The fact that Teva filed an ANDA and challenged the '329 patent rather than waiting to market generic versions of Merck's "once-daily" products is a compelling admission of both the value of Merck's

improved "once-weekly" invention and the evidentiary significance of Merck's commercial success as support for the validity of the '329 patent.

Because the Federal Circuit's rule is based on such clearly flawed premises, it should be reviewed immediately. Because of that court's exclusive jurisdiction, no percolation is needed or likely. The Federal Circuit has already invoked that rule when vacating another commercial success finding supporting a non-obviousness ruling reached after a bench trial. See *Syntex (U.S.A.) LLC* v. *Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005). Citing this case, the Federal Circuit expanded its new rule by stripping commercial success of its longstanding status – based on decisions of this Court – as a unique secondary consideration, declaring that a high degree of commercial success permits merely an inference that others have tried and failed to reach a solution. *Id.* at 1383. No more patentees, cases, or improvements in any field should be subjected to the Federal Circuit's flawed new "commercial success" rule.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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